

Attorney Docket No.: 930008-2202 (BOE0003US.NP)
Inventors: Klokke et al.
Serial No.: 10/541,894
Filing Date: December 2, 2005
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This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-23 (canceled).

Claim 24 (currently amended): A method for preparing granules for a pharmaceutical formulation comprising wetting a mixture of one or more corrosive active ingredients and one or more lipophilic retarding agents with an oily substance selected from the group consisting of neutral oil comprising caprylic and capric acid triglycerides, sesame oil, peanut oil, olive oil, almond oil, soybean oil, coconut oil, cottonseed oil, corn oil, rape oil, sunflower oil, wheat kernel oil, liquid paraffin, wax solutions in organic oil, and low viscosity wax; and granulating the wetted mixture so that granules for a pharmaceutical formulation are prepared.

Claim 25 (previously presented): The method of claim 24, wherein the mixture further comprises one or more excipients, fillers, flow-regulating agents, wetting agents or disintegrants, or a mixture thereof.

Claim 26 (previously presented): The method of claim 24, wherein the step of wetting the mixture is carried out by spraying.

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Claim 27 (previously presented): The method of claim 24, wherein the step of wetting the mixture is carried out at room temperature.

Claim 28 (currently amended): The method of claim 24, wherein at least one of the active ingredients is ~~corrosive~~ ~~or~~ hydrophilic.

Claim 29 (previously presented): The method of claim 24, wherein the active ingredient content is from 0.1% to 98% by weight of the total weight of the granules.

Claim 30 (previously presented): The method of claim 24, wherein the active ingredient content is from 0.5% to 70% by weight of the total weight of the granules.

Claim 31 (canceled).

Claim 32 (previously presented): The method of claim 24, wherein the lipophilic retarding agent is combined with a hydrogel matrix-forming agent, structural matrix-forming agent, or combination thereof.

Claim 33 (previously presented): The method of claim 24, wherein the lipophilic retarding agent is combined with a structural matrix-forming agent and water-soluble excipient.

Claim 34 (canceled).

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Claim 35 (previously presented): The method of claim 24, wherein the content of oily substance is from 0.2% to 20% by weight of the total weight of the granules.

Claim 36 (previously presented): The method of claim 24, wherein the content of oily substance is from 1.0% to 7.5% by weight of the total weight of the granules.

Claim 37 (previously presented): The method of claim 24, wherein the granules further comprise an outer phase of one or more retarding agents.

Claim 38 (previously presented): The method of claim 24, wherein the step of granulating the wetted mixture is carried out using a fluidized bed granulator or a plowshare mixer.

Claim 39 (previously presented): The method of claim 24, wherein the step of granulating the wetted mixture is carried out in the presence of a granule binder.

Claim 40 (previously presented): The method of claim 24, further comprising compressing the granules into tablets.

Claim 41 (currently amended): A method for preparing tablets comprising wetting a mixture of one or more corrosive active ingredients and one or more retarding agents with an oily substance selected from the group consisting of neutral oil comprising caprylic and capric acid triglycerides, sesame oil, peanut oil, olive oil,

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almond oil, soybean oil, coconut oil, cottonseed oil, corn oil, rape oil, sunflower oil, wheat kernel oil, liquid paraffin, wax solutions in organic oil, and low viscosity wax; granulating the wetted mixture so that granules are formed; and compressing the granules so that tablets are prepared.

Claim 42 (previously presented): The method of claim 41, further comprising mixing the granules with at least one excipient prior to the step of compressing the granules.

Claim 43 (previously presented): The method of claim 42, wherein the excipient is a filler, lubricant, flow-regulating agent, disintegrant, or a mixture thereof.

Claim 44 (previously presented): The method of claim 41, wherein the tablet further comprises a coating.

Claim 45 (previously presented): Granules prepared according to the method of claim 24.

Claim 46 (currently amended): Granules for a pharmaceutical formulation comprising a mixture of one or more corrosive active ingredients and one or more lipophilic retarding agents, wherein the mixture has been wetted with an oily substance selected from the group consisting of neutral oil comprising caprylic and capric acid triglycerides, sesame oil, peanut oil, olive oil, almond oil, soybean oil, coconut oil, cottonseed oil, corn oil, rape oil, sunflower oil, wheat kernel oil, liquid paraffin, wax solutions in organic oil, and low viscosity wax.

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Claim 47 (currently amended): Granules according to claim 46, wherein at least one of the active ingredients is ~~corrosive or~~ hydrophilic.

Claim 48 (previously presented): A tablet prepared according to the method of claim 41.